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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/936,514

09/14/2001

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018793-253

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7590

07/07/2009

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

07/07/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/936,514	<b>Applicant(s)</b> ABE ET AL.	
	<b>Examiner</b> CHRISTIAN L. FRONDA	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,9,12-16 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,9,12-16 and 25-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1, 3, 9, 12-16, and 25-31 are pending and under consideration in this Office Action.
2. The objection to claim 1 has been obviated by the claim amendment filed 03/25/2009.
3. The rejection of claims 1, 3, 9, 12-16, and 25-31 under 35 U.S.C. 112, second paragraph, as being indefinite has been obviated by the claim amendment filed 03/25/2009.
4. The rejection of claims 1, 3, 9, 12-16, and 25-31 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been obviated by the claim amendment filed 03/25/2009.
5. The rejection of claims 1, 3, 9, 11-16, 25-31 under 35 U.S.C. 103(a) as being unpatentable over Oriel et al. (reference of record) in view of Chen. (reference of record) has been withdrawn in view of the unexpected results shown in the Declaration Under 37 C.F.R. § 1.132 of Kiyoshi Ito filed 03/25/2009.

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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*Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. The terminal disclaimer filed on 03/25/2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 6,849,432 has been reviewed and is NOT accepted.

The person who signed the terminal disclaimer is not recognized as an officer of the assignee, and he/she has not been established as being authorized to act on behalf of the assignee. See MPEP § 324.

An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c). Thus, the nonstatutory obviousness-type double patenting rejection stands which is reproduced below.

8. Claims 1, 3, 9, 12-16, and 25-31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,849,432 in view of the combined teachings of Oriel et al. (WO 99/55719; reference of record) and Chen. (J Biol Chem. 1967 Jan 25;242(2):173-81; reference of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because as explained below.

Claims 1-4 of U.S. Patent No. 6,849,432 encompass a process for producing an amide compound, comprising reacting a microorganism fungus body containing nitrile hydratase or a processed product of the microorganism fungus body with a nitrile compound in an aqueous medium.

Oriel et al. teach a process where BR449 cells are contacted with acrylonitrile to produce a solution containing acrylamide, the said BR449 cells are separated from the reaction mixture, the said acrylamide solution is treated with activated charcoal (an activated carbon), to remove contaminants and the acrylamide is concentrated or precipitated by distillation or evaporation under reduced pressure (see entire publication especially p. 17, line 17 to p.18, line 24). Oriel et al. further teach that other unsaturated aliphatic nitrile compounds such as crotononitrile and methacrylonitrile that can be converted using the nitrile hydratase of BR449 (see p. 36, lines 27-28).

Chen teach process steps for removing lipid impurities by acid-charcoal treatment, using an acidic range of pH 3 to pH 7 at 2°C where the charcoal is made from wood (see entire publication, especially Figs. 1-4 and pp. 174-177). The reference of Chen clearly shows that acid-charcoal treatment, using an acidic range of pH 3 to pH 7 at 2°C, is used for removing lipid impurities, which are expected to be contained within the recited “microorganism fungus body”, and “processed product of the microorganism fungus body”.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the process of Oriel et al. such that the amide solution is produced by microorganism fungus body containing nitrile hydratase or a processed product of the microorganism fungus body as taught by U.S. Patent No. 6,849,432, and the amide solution is subjected to acid-charcoal treatment as taught by Chen. One of ordinary skill in the art at the time the invention was made would have been motivated to do this for the purposes of having a simple and beneficial purification process that produces an amide compound and removes impurities including lipid impurities.

The reference of Oriel et al. clearly shows that activated charcoal, which is known in the art to be treated with acid in order to activate the charcoal, was used to purify acrylamide from the reaction mixture. Therefore, one of ordinary skill in the art at the time the invention was made would recognize and predict that nitrile compounds containing an unsaturated bond are stable in acidic conditions. Furthermore, the process of Oriel et al. would inherently remove

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impurities including proteins since the process involves not only contacting the solution with activated carbon but also includes steps for concentrating or precipitating by distillation or evaporation the amide solution, thereby removing contaminating proteins. The reference of Chen clearly shows that acid-charcoal treatment, using an acidic range of pH 3 to pH 7 at 2°C, is used for removing lipid impurities, which are expected to be contained within the recited “microorganism fungus body”, and “processed product of the microorganism fungus body”. Therefore, one of ordinary skill in the art at the time the invention was made would recognize and predict that in order to remove such lipid impurities from the reaction mixture, acid-charcoal treatment using an acidic range of pH 3 to pH 7 at 2°C is required. Furthermore, one of ordinary skill in the art at the time the invention was made would try to optimize the pH and temperature of the reaction mixture in order to obtain the highest, purified yield of the amide compound from the reaction mixture.

### ***Conclusion***

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/

Primary Examiner

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